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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,897	03/06/2002	Aneas Antoine	1417G P 703	9171

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EXAMINER

VIRDI, SUNDEEP

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/091,897	Applicant(s) ANTOINE, ANEAS	
	Examiner Sundeep S Virdi	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 1-8, 10 and 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas (WO 98/13006) in view of Hiblar et al (US 2002/0072706) or Parker et al (US 2003/0093037).

With regards to claim 1, Aneas discloses a device for connection between a closed recipient and a container comprising a neck whose opening is closed by a stopper. Aneas discloses a base adapted to be mounted on a recipient (3) and comprising a sleeve (12) with an inner bore (12a). Aneas further discloses a hollow needle (5), a plunger (15), adapted to slide in the bore and has an edge of sleeve opposite a stopper (3b) provided with stop means (18) adapted to cooperate with complementary means (16) provided on the plunger (15) to lock it in a position of transfer.

With regards to claim 6, Aneas discloses hooks (54) that are provided with a nose.

With regards to claim 7, the hooks project radially with respect to the sleeve.

With regards to claim 8, Aneas discloses a second sleeve (22) disposed radially outside an interior sleeve (12).

With regards to claim 10, Aneas discloses a means for temporarily stopping the plunger in the disengaged position and states that the invention is "in position fastened and locked on a first receptacle, and in the inactivated position of the plunger comprising the perforating means."

Additionally, with regards to claim 12, Aneas discloses a ready-to-use assembly comprising a closed recipient containing a product (2), with the recipient being provided with a neck (2a) whose opening is closed by a stopper (3), with a connection device (1) mounted on said recipient (see figs. 2-4).

However, Aneas does not disclose a needle with a non-circular cross section, a sleeve with a non-circular cross-section, such that the needle can slide in the sleeve without the possibility of rotation.

Hiblar et al discloses a transluminal drug delivery catheter that teaches the use of a needle with a non-circular cross section (30) in conjunction with a non-circular sleeve (34) (see paragraph 0061) in order to prevent rotation of the needle within the sleeve. It would have been obvious to one of ordinary skill in the art to modify the needle of Aneas and incorporate a non-circular needle/sleeve device as taught by Hiblar in order to prevent unwanted rotation of the needle.

Parker et al disclose a hypodermic needle syringe that teaches the use of a non-circular needle hub (4) in conjunction with a non-circular sleeve (1.2) (see paragraph 0030) in order to prevent axial rotation of the needle relative to the sleeve. While the needle itself is not taught to be non-circular, it would be an obvious modification to one of ordinary skill in the art to see the non-circular hub interacting with the non-circular

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sleeve and come to the realization that making the needle itself non-circular to fit into a non-circular sleeve will also prevent rotation of the needle with respect to the sleeve, as taught by Parker et al. It would be obvious to one of ordinary skill in the art to modify the needle of Aneas and incorporate a non-circular needle/sleeve device as taught by Parker in order to prevent unwanted rotation of the needle.

Claim 2 narrows the shape of the cross-section of the needle to an oval outer cross section with the sleeve having an oval cross-section. Hiblar and Parker et al teaches using a needle and sleeve with a non-circular cross section in the same field of endeavor in order to prevent the rotation of the spike.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an oval cross section since the reference discloses using a non-circular cross section and oval is a non-circular shape.

With regards to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polygonal outer cross-section with the sleeve's inner cross-section also being polygonal (see above discussion).

Additionally, the choice of a non-circular cross section in claims 1,2 and 3 would have been an obvious design choice. It would have been an obvious engineering design modification to change the shape of the cross section of the needle to a non-circular shape. Further, changing the shape of the needle does not affect the integrity of the invention.

With regards to claims 4 and 5, Aneas discloses the claimed invention as discussed above. However, Aneas does not teach that the stop means comprise

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elastically deformable hooks while the complementary means on the plunger are bearing surfaces on a flange in one piece with the needle. However, Aneas does teach the same elements in reverse. Aneas teaches a stop means that comprises elastically deformable hooks (16) on the plunger with a complementary bearing surface (18) on the sleeve. The integrity of the invention is not adversely impacted or affected by where the hooks and bearing surface are placed. The effect is the same regardless of if the hooks are on the plunger or if they're on the sleeve. It would have been obvious to one of ordinary skill in the art to rearrange the device and place the hooks on the plunger and with the complementary means on the sleeve to act as a stop means. The effect is similar regardless of how the hooks and bearing surfaces are arranged.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Hiblar or Parker and further in view of Thibault et al (WO 99/53886). Aneas, Hiblar and Parker are discussed above in paragraph.

Aneas and Hiblar or Aneas and Parker et al do not disclose a stop means comprising at least one hollow made on the outer surface of the needle and at least one projection extending, from the inner radial surface of said sleeve, in the direction of a central axis of a bore adapted to be engaged with the hollow to maintain needle in position.

Thibault teaches using a hollow on the outer surface of a needle (see figure 10, hollow just above 476) that is engaged by a projection that extends from the inner radial surface of a sleeve (see figure 11, 478; see also page 14 lines 27-29).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Aneas by including a hollow in the needle and a projection on the inner surface of the sleeve in order to keep the needle in a disengaged position.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas and Hiblar or Aneas and Parker further in view of Manera.

Aneas and Hiblar or Aneas and Parker disclose the claimed invention as discussed above. However, they do not teach the use of ribs that form a rigid barrier to rotation.

Manera teaches using ribs connecting an inner sleeve (12) with a plunger (15) in order to form a rigid barrier for blocking rotation of the plunger with respect to the inner sleeve (column 4, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ribs disclosed in Manera for the same purpose Manera teaches (to prevent rotation between two radial surfaces) and modify the ribs for use between an inner and an outer sleeve to prevent rotation of the sleeves with respect to each other instead of between a plunger and sleeve in Aneas and Hiblar or Aneas and Parker.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-3, 6-10, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of Hiblar et al (US 2002/0072706) or Parker et al (US 2003/0093037).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application would be obvious to one of ordinary skill in the art in light of the teaching of the secondary references.

All the limitations of claims 1-3, 6-10, 12 and 13 are present in claims 1, 2, 5 and 6 of Aneas as discussed above with the exception of a needle and sleeve with a non-circular cross section. Hiblar et al (US 2002/0072706) and Parker et al (US 2003/0093037) et al disclose the use of a needle with a non-circular cross section in conjunction with a sleeve with a non-circular cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas with a non-circular cross-section as disclosed in Hiblar et al or Parker et al in order to prevent rotation of the needle.

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Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of Hiblar or Parker and further in view of WO 99/53886 (Thibault et al).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application would be obvious to one of ordinary skill in the art in light of the teaching of the secondary reference Thibault et al.

All the limitations of claims 11 are present in claims 1, 2, 5 and 6 of Aneas in conjunction with the teachings of Hiblar or Aneas in conjunction with the teachings of Parker as discussed above with the exception of at least one hollow made on the outer surface of a needle and at least one projection extending from the inner radial surface of the sleeve, in the direction of a central axis of a bore such that the projection is adapted to be engaged in the hollow of the needle in order to maintain the needle in a first stopped position. Thibault et al discloses the use of a spike with a non-circular cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Aneas to incorporate a hollow on the outer surface of the needle and at least one projection extending from the inner radial surface of the sleeve, in the direction of a central axis of the bore, such that the projection is adapted to be engaged in the hollow of the needle in order to maintain the needle in a first stopped position.

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13. Claims 4 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5 and 6 of U.S. Patent No. 6,070,623 (Aneas) in view of Hiblar or Parker.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the additional elements claimed in the present application would be obvious to one of ordinary skill in the art in light of the teaching of the secondary reference Martin.

All the limitations of claims 4 and 5 are present in claims 1, 2, 5 and 6 of Aneas in conjunction with the teachings of Hiblar or Aneas in conjunction with the teachings of Parker as discussed above with the exception of a stop means comprising elastically deformable hooks with complementary means comprising bearing surfaces made on a flange in one piece with a needle, with the needle and flange together constituting a plunger as in claim 4 or a flange with openings for passage of hooks as in claim 5.

Aneas does teach the same elements in reverse. Aneas teaches a stop means that comprises elastically deformable hooks (16) on the plunger with a complementary bearing surface (18) on the sleeve. The integrity of the invention is not adversely impacted or affected by where the hooks and bearing surface are placed. The effect is the same regardless of if the hooks are on the plunger or if they're on the sleeve. It would have been obvious to one of ordinary skill in the art to rearrange the device and place the hooks on the plunger and with the complementary means on the sleeve to act as a stop means. The effect is similar regardless of how the hooks and bearing surfaces are arranged.

Response to Arguments

5. Applicant's arguments, see page 9, first paragraph, filed 11/16/04, with respect to the rejection(s) of claim(s) 1-11 under U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hiblar et al or Parker et al. Examiner agrees with applicant that previously used reference Pfleiderer does not contain the limitation of a sleeve covering the needle. However, as discussed above, Hiblar and Parker both contain this limitation and the claims have been rejected accordingly.

Examiner disagrees with applicant's arguments on page 10, second paragraph. Applicant claims that preventing rotation is not necessary in Aneas, since the connection device of Aneas is fastened to the bottle. This is not persuasive because the same thing could be said of applicant's invention. It too is fastened to the bottle. Also, preventing rotation of the needle/plunger assembly with respect to the sleeve was clearly a consideration of the inventor in Aneas as demonstrated in column 4, lines 49-51. While examiner agrees that Pfleiderer was not a properly combinable reference due to the lack of a sleeve, examiner disagrees with applicant's argument that rotation was not a concern in Aneas that therefore there could never be motivation to combine a reference that addresses the problem of needle/plunger rotation. A person of ordinary skill reading Aneas would see that rotation of the needle/plunger assembly was a concern and upon seeing the references utilized in this office action (Hiblar and Parker) would see the use of a non-circular needle in conjunction with a non-circular sleeve

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would address the problem of rotation and thereby have motivation to combine the references.

With respect to applicant's arguments on page 9, third paragraph, examiner finds the arguments regarding the limitation of "an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer" unpersuasive. Aneas discloses an edge of said sleeve (12) opposite said stopper (3) provided with stop means (18) adapted to cooperate with a complementary means (16) provided on said plunger (15) to lock it in position of transfer. The edge of sleeve 12 adjacent to the stopper 3 is the surface immediately adjacent to the stopper 3 directly above it. The edge opposite the stopper is the top edge of 18, which meets applicant's limitation. The complementary means (16) are located on plunger and lock the plunger in position of transfer (see figure 1).

With respect to applicant's arguments on page 11, first paragraph, examiner has made a new rejection as discussed above.

With respect to applicant's arguments on page 13, second paragraph, examiner finds applicant's arguments unpersuasive. Claim 11 states that the projection and hollow engage to maintain the plunger in the first position. This is what the projection (476) and hollow (see figure 10, hollow just above 476) taught by Thibault do. They maintain the plunger in a first position. Also, claim 11 depends from claim 10, which states "stopping plunger in said disengaged position." Again, the projection and hollow in Thibault maintain the plunger in a disengaged position, as is clear in figure 9. On

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page 13 applicant asserts that the arrangement of Thibault must "operate to lock the piercing member in a transfer position with respect to the stopper." This limitation is not found in claim 1, 10 or 11. The claims clearly indicate that the projection and hollow must maintain the plunger in a disengaged or first position, which is what Thibault teaches.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant maintains that Thibault is not directed to an improved transferset or similar connection. This is not correct. Thibault is directed to a plastic closure for vials and other medical containers. The invention can be used to secure a fluid transferset on a vial. An inventor skilled in the art could look to Thibault in assisting him in developing a new connection device. For the above reasons applicant's arguments regarding the motivation to combine Thibault are unpersuasive.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Choudhary (6,689,107) discloses a needle assemble that teaches the use of a needle with a non-circular cross section in conjunction with a

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sleeve. Stringfellow (6,053,425) discloses an injection device that teaches the use of a needle with a non-circular cross-section in conjunction with a bore that has a non-circular cross-section.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeep S Virdi whose telephone number is 571-272-4969. The examiner can normally be reached on M-F 9am-5:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sundeep Virdi
Art Unit 3763



MICHAEL J. HAYES
PRIMARY EXAMINER